2015 Louisiana Vaccines for Children Program Thermometer Guide

Louisiana Department of Health and Hospitals
Office of Public Health
Immunization Program

General Requirements

The Centers for Disease Control and Prevention (CDC) and the Louisiana Vaccines for Children (VFC) Program within the state Department of Health and Hospitals, Office of Public Health, Immunization Program require that healthcare providers who receive VFC vaccines have a calibrated thermometer with a current certificate issued by an International Laboratory Accreditation Cooperation (ILAC)-accredited laboratory. If the certificate is not ILAC-accredited, the certificate must contain measurement results and a statement indicating that it meets International Organization for Standardization (ISO) 17025 standards. All certificates must contain the following:

- Name of the device (optional)
- Model number
- Serial number
- Date of calibration
- Measurement results indicating that the device passed test and the documented uncertainty is within suitable limits (+/-1^{o}F (0.5^{o}C) is recommended).

At the same time, the CDC recommends[1] the use of a digital data logger thermometer with the following features:

- Detachable probe in a buffered material (e.g., glycol) with continuous monitoring capabilities
- Easily-readable temperature from the outside of the unit
- Alarm for out-of-range temperatures
- Current, minimum, and maximum temperatures
- Reset button
- Low-battery indicator
- Accuracy of +/-1^{o}F (0.5^{o}C)
- Memory storage for at least 4,000 readings (the device must also not write over old data and stop recording when memory is full)
- User-programmable logging interval (or reading rate)

Listings of ILAC-accredited calibration laboratories may be obtained through the following participating organizations:

American Association for Laboratory Accreditation (A2LA)
http://www.a2la.org

Laboratory Accreditation Bureau (L-A-B)
http://www.l-a-b.com

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[1]CDC's recommendation on data-logger use may become a requirement in the near future.

ANSI-ASQ National Accreditation Board (ACLASS/FQS)
http://www.aclasscorp.com
http://www.fqsforensics.org

Perry Johnson Laboratory Accreditation, Inc. (PJLA)
http://www.pjlabs.com

Sample of ILAC-Accredited Laboratories Near Louisiana

ASI Calibration Labs
http://www.asicallab.com
A2LA Certificate No. 1876.01
1644 Varner Dr.
Mobile, AL 36693
Telephone: (877) 240-6392

Control Company
http://www.control3.com
A2LA Certificate No. 1750.01
4455 Rex Rd.
Friendswood, TX 77546
Telephone: (281) 482-1714

Global Instrumentation Services
http://www.globalinstserv.com
L-A-B Certificate No. L2268
800 W. Sam Houston Pkwy., Ste.188
Houston, TX 77042
Telephone: (888) 277-7450

CDC also requires that thermometers be placed in a central area of the storage unit directly with the vaccines in order to properly measure vaccine temperature. Thermometers should not be placed in the doors, near or against the walls, close to vents, or on the floor of the unit.

Continuous Monitoring

In following the CDC's guidance, the Louisiana VFC Program *recommends* the use of a continuous monitoring data logger for units that store VFC vaccine. This is a logger with the ability to record/graph temperatures over time. It should be noted, however, that a high/low recording thermometer is not the same as a continuous-monitoring thermometer. High/low devices offer only basic information about the maximum and minimum temperature a thermometer has reached, while continuous-monitoring devices are capable of digitally storing *all* past temperatures for future reference.

Internal vs. external temperature probes

Both the CDC and the Louisiana VFC Program *strongly* encourage the use of loggers with an external probe in glycol. Research conducted by the National Institute of Standards and Technology concluded that:

"Data loggers featuring an external probe kept in a glycol-filled bottle provide effective, continuous temperature monitoring of stored vaccines. This setup mimics the conditions and properties of stored vaccines. Provided that a structured validation protocol is followed, digital data loggers of this type can be used to stably monitor vaccine temperature for many months or years. By contrast, loggers featuring sensors designed to record air temperature proved unacceptable for use as vaccine temperature monitors."[2]

High/Low Alarm

A data logger should have a high and low alarm that alerts the provider any time a refrigerator or freezer temperature goes outside the recommended range.

Min/Max Display

A large, easy-to-read display is very useful when monitoring vaccine temperature, including the twice-a-day readings expected of providers. Loggers that use confusing symbols/icons as well as small, hard-to-read displays should be avoided. A logger should also have the ability to display (and reset) minimum/maximum temperatures between readings.

Accuracy

Thermometers should have a high accuracy of **+/- 1°F (+/- 0.5°C)**. This information should be contained in the device's Certificate of Traceability and Calibration Testing (also known as Report of Calibration).

Low-Battery Indicator

Notification of low-battery status is essential for accurate vaccine-temperature recording. Such notification gives a provider advanced warning and ensures that vaccine monitoring is not interrupted or incomplete.

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[2]Chojnacky, M.; Miller, W.; and Strouse, G. *Data Logger Thermometers for Vaccine Temperature Monitoring*, http://nvlpubs.nist.gov/nistpubs/ir/2012/NIST.IR.7899.pdf.

Software

Some digital devices do not include free graphing software and will require an additional purchase. It is, therefore, recommended that the provider refer to the manufacturer or distributor for full details on the device chosen.

Wireless and Cloud-Based Systems

Wi-Fi and Ethernet-based systems are relative newcomers to the field of continuous temperature monitoring but are gaining popularity. While more costly than stand-alone units, the increase in convenience and accessibility makes them a smart purchase. Some of the newer systems send temperature data directly to a cloud storage site which can be accessed in real time from any computer in the world. Real-time feedback is especially useful when addressing time-sensitive vaccine excursions. Providers will likely need a competent IT staff person (or an employee with strong technical skills) to help implement such a system.

Back-Up Continuous Monitoring Thermometers/Loggers

CDC *requires* having at least one calibrated back-up thermometer (i.e., a thermometer not being used to monitor any other vaccine storage unit) with a current, valid certificate of calibration in case something happens to the primary thermometer or if the primary thermometer must be sent to the laboratory for calibration.

A back-up thermometer should have the same features as the primary device (for example, a detachable probe in a buffered material such as glycol). In addition, the CDC recommends that the back-up thermometer have a different calibration schedule from that of the primary device so that the back-up is available when the primary thermometer is sent for calibration.

Equipment Options

Based on the above guidelines, the following is a brief list of equipment options that meet or exceed CDC and Louisiana VFC Program requirements and/or recommendations. This list is by no means exhaustive and merely provides examples of continuous-monitoring data loggers to consider when purchasing.

Disclaimer

*As a state-government entity, the Louisiana VFC Program does **not** endorse any specific brand or product. The terms and conditions of a purchase are ultimately between a provider and its vendor.*

Online Vendors and Manufacturers

Providers have many options when it comes to purchasing data loggers. The following are examples of vendors and manufacturers:

Vendors

Control Solutions, Inc.: http://www.vfcdataloggers.com
MicroDaq.com, Ltd.: http://www.microdaq.com
CAS DataLoggers: http://www.dataloggerinc.com
ThermoWorks: http://www.thermoworks.com
Thermco Products: http://www.thermcoproducts.com

Manufacturers

Dickson: http://www.dicksondata.com
LogTag Recorders Ltd.: http://www.logtagrecorders.com
Berlinger & Co. AG: http://www.berlinger.ch/?id=4&L=1
Lascar: http://www.lascarelectronics.com
DeltaTrak: http://www.deltatrak.com
Cole-Parmer: http://www.coleparmer.com

Sample Data Loggers

Fridge-tag® 2 Electronic Temperature Monitoring During Storage with USB Port

The Fridge-tag® 2 can be positioned outside the refrigerator. The external cable sensor is placed next to the goods to be monitored. The display shows the temperature measured by the external sensor. The PDF report shows additionally the temperature which the internal sensor of the Fridge-tag® 2 has measured on the time of the alarm. This means that the provider receives information on temperature conditions outside the refrigerator when the alarm is triggered. The device's external sensor can be equipped optionally with a bottle filled with bio-safe glycol.

FEATURES:

- NIST Traceable with Certificate
- Technician Daily Verification Log
- Removable Probe
- True Seal Flat Ribbon Probe Cable
- Bio-Safe Glycol / Water Probe Medium
- Current Temperature Display
- No Software Needed for Computer Interface
- 30 Day Status on Screen
- Press for 30-Days of Min/Max History
- PDF report... 60 days of temperature & alarm data
- High/Low Alarm
- 43,200 Temperature Observations Monthly
- Meets 21 CFR Part 11 requirements
- Accuracy ±1°F (0.5°C)

For more information, visit: http://www.berlinger.ch/?id=4&L=1

LogTag® TRED30-7 Temperature Recorder with 30-Day Summary Display and Remote Probe

This data logger measures and stores up to 7,770 temperature readings over a measurement range of -40oF to 210oF (-40°C to 99°C) measurement range from a remote temperature probe. Statistical temperature and duration readings for up to 30 days can be reviewed on the display. The visual display of current temperature and previous alarms is an important feature in "static" applications such as cool rooms and refrigerators. The display arrangement is designed to show "at a glance" if temperature violations have occurred during the current day and up to the previous 29 days. The display also shows the current temperature reading, the current time, recording status and battery status. Details of any excursions can be checked directly by inspecting the statistics history on the recorder's display or in more detail by downloading the logged data via a standard LogTag® Interface cradle to LogTag® Analyzer. If a reading outside the pre-set "Alarm" limits is recorded at any time, a "day alarm indicator" appears on the display.

FEATURES:

- NIST Traceable with Certificate
- Data Logging – Records time and temperature data for later download
- Day alarm summary - Displays in calendar-like format alarm triggers for up to the last 30 days
- Current time & temperature - Shows the current time and temperature when not in review mode
- Push Button Logging start with optional delayed start or specific Time & Date start
- Rapid Download! Takes only seconds to download recordings
- 'Pre-Start' logging - LogTag® can be configured to record even if it has not been started.
- High performance at low cost
- Thin flat case – Fits easily into packaging and thin enough to be easily mailed "letter rate".
- Real time clock records time & temperature simultaneously

- Easy to use LogTag Analyzer software that runs on any PC configures LogTag® for recording then downloads resulting data for analysis. Data can also be exported to fomats compatible with other applications such as Excel
- Re-calibration to achieve higher accuracy possible
- High quality gold plated remote sensor connector
- Interchangeable Remote Probes – LogTag® remote temperature probes are interchangeable provided they are changed with LogTag® ST100 type remote temperature sensors.

For more information, visit: http://www.logtagrecorders.com

FlashLink Certified Vaccine Data Logger with Glycol Bottle (WHO prequalified), Model 20932

The FlashLink Certified Vaccine Data Logger with Glycol Bottle provides an accurate reading, programmable alarms and sampling intervals, and a USB connection to quickly and easily download temperature data. The FlashLink Certified Vaccine Data Logger with Glycol Bottle can be programmed to start automatically or with the option for a delayed start allowing the Glycol Bottle sufficient time to stabilize to the refrigerator temperature. Temperature data is easily downloaded and analyzed using DeltaTrak's FlashPDF Program Manager Software.

FEATURES:

- Large, easy to read LCD Display
- Certified, NIST traceable
- Remaining Battery Indicator on LCD (low battery)
- Detachable external temperature sensor, sealed in 5mL glycol bottle
- Hi/Low programmable alarms for out of range conditions
- User programmable logging intervals
- USB Connection
- Temp range -40˚F to 104˚F / -40˚C to 40˚C
- 16,112 data points

For more information, visit: http://www.deltatrak.com

Additional Equipment

The following are additional equipment a provider may consider when assessing its vaccine-storage needs.

Alarm Telephone Dialers

These devices, though a relatively old technology, may be useful to providers with limited internet connectivity or recurrent power outages. They are sold by several manufacturers in varied models, styles, and prices to choose from.

Alarm telephone dialers are designed to call pre-determined telephone numbers when temperatures go out of range and are a simple and reliable alarm option, provided the system is accurate. Maintaining a temperature reading that mirrors a current calibrated continuous logger is imperative to the usefulness of a dialer.

Providers have many options when it comes to purchasing dialers. The following are examples of manufacturers:

Sensaphone: http://www.sensaphone.com
Dickson: http://www.dicksondata.com
United Security Products: http://www.unitedsecurity.com
Security Product Solutions: http://www.securityproductsolutions.com

Emergency Power Generators

Disruption in the power supply is one of the most frequent causes of costly vaccine loss, since it does not take long for a refrigerator or freezer to warm up due to a power outage and thus compromise vaccine integrity. Healthcare providers (especially those in rural or coastal areas, or those storing large vaccine inventories) should seriously consider having an emergency power generator in place should an emergency occur. If a provider already has such a unit in place, it must make sure a vaccine refrigerator and freezer are connected to that power circuit.

According to the CDC, emergency power generators should be tested quarterly and receive maintenance at least annually (check manufacturer specifications for test procedures and maintenance schedules). Back-up generators should be of a sufficient capacity to run continuously for 72 hours if necessary. Plans should be made to ensure that an adequate supply of fuel is on hand.[3]

There are many manufacturers and vendors selling generators. Below are a few examples:

Generac: http://www.generac.com
GE Generator Systems: http://www.gegenerators.com
Kohler: http://www.kohlergenerators.com
Briggs & Stratton: http://www.briggsandstratton.com/us/en/generators

Louisiana VFC Program Contact Information

For more information on thermometers/data loggers or any other matter concerning VFC requirements or recommendations, please contact the Louisiana VFC Program at (504) 838-5300.

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[3]Centers for Disease Control and Prevention. *Vaccine Storage & Handling Toolkit: May 2014*, http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf.